IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

ASSOCIATION OF ARKANSAS COUNTIES; ASSOCIATION OF ARKANSAS COUNTIES RISK MANAGEMENT FUND; and ASSOCIATION OF ARKANSAS COUNTIES WORKERS' COMPENSATION TRUST; Plaintiffs, v. PURDUE PHARMA INC.; THE PURDUE FREDERICK COMPANY; CEPHALON, INC.; PHARMACEUTICALS USA, INC.; JANSSEN PHARMACEUTICALS, INC.; JOHNSON & JOHNSON; ENDO HEALTH SOLUTIONS, INC.; WATSON LABORATORIES, INC.; ACTAVIS PHARMA, INC.; ACTAVIS LLC; AMERISOURCEBERGEN DRUG CORPORATION; CARDINAL HEALTH, INC.; and McKESSON CORPORATION; Defendants.	CASE NO. 4:17cv831-JLH **JURY TRIAL DEMANDED**

FILED
U.S. DISTRICT COURT
EASTERN DISTRICT ARKANSAS
DEC 14 2017
JAMES W. McCORMACK, CLERK
By: DEP CLERK

COMPLAINT

Plaintiffs, ASSOCIATION OF ARKANSAS COUNTIES, ASSOCIATION OF ARKANSAS COUNTIES RISK MANAGEMENT FUND, and ASSOCIATION OF ARKANSAS COUNTIES WORKERS' COMPENSATION TRUST, allege as follows:

This case assigned to District Judge Holmes
and to Magistrate Judge Volpe

I. INTRODUCTION

1. Defendants manufacture, market, distribute, and sell prescription opioids (hereinafter "opioids"), including brand-name drugs like Oxycontin and Percocet, and generics like oxycodone and hydrodone, which are powerful narcotic painkillers. Historically, because they were considered too addictive and debilitating for the treatment of chronic pain (like back pain,

migraines and arthritis), opioids were used only to treat short-term acute pain or for palliative (end-of-life) care.

2. However, by the late 1990s, and continuing today, opioid manufacturers began a marketing scheme designed to persuade doctors and patients that opioids can and should be used for chronic pain, a far broader group of patients much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain. As to the risks, Defendants falsely and misleadingly, and contrary to the language of their drugs' labels: (1) downplayed the serious risk of addiction; (2) promoted the concept of "pseudoaddiction" and thus advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. Conversely, Defendants also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no "good evidence" to support Defendants' claims.

3. Defendants disseminated these common messages to reverse the popular and medical understanding of opioids. They disseminated these messages directly, through their sales representatives, and in speaker groups led by physicians Defendants recruited for their support of Defendants' marketing messages. Borrowing a page from Big Tobacco's playbook, Defendants also worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as "key opinion leaders" ("KOLs") and (b) funding, assisting, directing,

and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups"). Defendants then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, Continuing Medical Education ("CME") programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, Defendants persuaded doctors and patients that what they had long known – that opioids are addictive drugs, unsafe in most circumstances for long-term use – was untrue, and quite the opposite, that the compassionate treatment of pain required opioids.

4. Each Defendant knew that its misrepresentations of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of each Defendant's misrepresentations has been confirmed by the U.S. Food and Drug Administration ("FDA") and the Centers for Disease Control and Prevention ("CDC"), including by the CDC in its Guideline for Prescribing Opioids for Chronic Pain, issued in 2016 and approved by the FDA ("2016 CDC Guideline"). Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc. and Purdue Pharma L.P., have also entered into settlements agreements with public entities that prohibit them from making many of the misrepresentations identified in this Complaint in other jurisdictions. Yet even now, each Defendant continues to misrepresent the risks and benefits of long-term opioid use in Arkansas and continues to fail to correct its past misrepresentations.

5. Defendants also formed an opioid marketing enterprise in violation of Arkansas law for the purpose of illegally promoting the widespread use of opioids for chronic pain.

6. Defendants' efforts were wildly successful. Opioids are now the most prescribed class of drugs; they generated $11 billion in revenue for drug companies in 2014 alone. In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain." This epidemic, fueled by opioids lawfully prescribed by doctors, has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or legitimately obtain opioids, they often turn to the street to buy prescription opioids or even heroin. Arkansas is now awash in opioids and engulfed in a public health crisis the likes of which have not been seen before.

7. The result of Arkansas's opioid crisis has been catastrophic. Opioids have become the main source of unintentional drug overdose in the state and, due to the vast supply of opioids, the number of annual deaths attributable to unintentional drug overdoses has rapidly increased in recent years. The dramatic increase in opioid prescriptions to treat chronic pain has resulted in a population of addicts who seek drugs from doctors. Efforts by physicians to reverse course for a chronic pain patient with long term dependence on opioids are often thwarted by a secondary criminal market well-stocked by a pipeline of drugs that are diverted to supply these patients.

8. Prescription opioid abuse has not displaced heroin, but rather triggered a resurgence in its use, imposing additional burdens on Arkansas' local governments that address heroin use addiction. Individuals who are addicted to prescription opioids often transition to heroin because it is a less expensive, readily available alternative that provides a similar high.

9. Arkansas citizens suffer from chronic pain, which takes an enormous toll on their health, lives and families. These patients deserve both appropriate care and the ability to make decisions based on accurate, complete information about treatment risks and benefits. But Defendants' deceptive marketing campaign deprived Arkansas patients and their doctors of the ability to make informed medical decisions and, instead, caused important, sometimes life-or-death decisions to be made based not on science, but on hype. Defendants deprived patients, their doctors, and health care payors of the chance to exercise informed judgment and subjected them to enormous costs and suffering.

10. Defendants' conduct has also foreseeably exacted a financial burden on Arkansas' citizens, including Plaintiffs. Plaintiffs AACRMF and AACWCT ("the Trusts") have unnecessarily spent money on opioid prescriptions for chronic pain. In addition, both the AACRMF and AACWCT have spent considerably more funds on costs directly attributable to the flood of opioids Defendants unleashed on the State, including costs for addiction treatment and the treatment of babies born addicted to opioids.

11. To redress and punish these violations of law, Plaintiffs seek damages for the amounts the AACRMF and AACWCT have paid for excessive opioid prescriptions and in connection with the results of those prescriptions (e.g., addiction treatment costs).

II. JURISDICTION AND VENUE

12. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332 as there is complete diversity of citizenship between the parties, and the amount in controversy exceeds $75,000.

13. This Court has personal jurisdiction over Defendants as they conduct business in Arkansas, purposefully direct or directed their actions toward Arkansas, and/or have the requisite

minimum contacts with Arkansas necessary to constitutionally permit the Court to exercise jurisdiction.

14. Venue is proper in this court under 28 U.S.C. § 1391(b)(2) because a substantial part of the events and omissions giving rise to the claim occurred in the Eastern District of Arkansas.

III. PARTIES

A. Plaintiffs

15. Plaintiff, the ASSOCIATION OF ARKANSAS COUNTIES ("AAC"), is an association of Arkansas counties that is the official agency of Arkansas counties, and provides programs and services to Arkansas counties under Arkansas law. *See* Ark. Code Ann. § 14-20-107. The AAC is a citizen of the State of Arkansas. The AAC's Administrative Office is located at 1415 W 3rd St, Little Rock, AR 72201.

16. Plaintiff, the ASSOCIATION OF ARKANSAS COUNTIES RISK MANAGEMENT FUND ("AACRMF"), is a multi-county, self-funded trust of Arkansas counties formed for the promotion of their general welfare and for legal services, including defense and limited financial protection when they have been sued. The AACRMF is a citizen of the State of Arkansas. The AACRMF's Administrative Office is located at 1415 W 3rd St, Little Rock, AR 72201.

17. Plaintiff, the ASSOCIATION OF ARKANSAS COUNTIES WORKERS' COMPENSATION TRUST ("AACWCT"), is a multi-employer, self-funded trust of Arkansas counties. The AACWCT assists counties to meet their statutory responsibilities for on-the-job employee injuries, death, wages, and loss-of-time claims. The AACWCT is a citizen of the State

of Arkansas. The AACWCT's Administrative Office is located at 1415 W 3rd St, Little Rock, AR 72201

B. Manufacturer Defendants

18. PURDUE PHARMA L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of business in Stamford, Connecticut, and THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, "Purdue"). Purdue manufactures, promotes, sells, and distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the U.S. and Arkansas. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

19. CEPHALON, INC. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. ("Teva USA") is a wholly-owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon in October 2011. Cephalon, Inc. manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the U.S. and Arkansas. Actiq and Fentora have been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd.

conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in Arkansas, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events. Teva Ltd. has directed Cephalon, Inc. to disclose that it is a wholly-owned subsidiary of Teva Ltd. on prescription savings cards distributed in Arkansas, indicating Teva Ltd. would be responsible for covering certain co-pay costs. All of Cephalon's promotional websites, including those for Breakthrough pain is a short-term flare of moderate-to-severe pain in patients with otherwise stable persistent pain, Actiq and Fentora, prominently display Teva Ltd.'s logo. Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales." Through interrelated operations like these, Teva Ltd. operates in Arkansas and the rest of the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. (Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as "Cephalon.")

20. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with its

principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are referred to as "Janssen.") Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and Arkansas, including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

21. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a wholly-owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. (Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. are referred to as "Endo.") Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and Arkansas. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012.

Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and Arkansas, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

22. WATSON LABORATORIES, INC. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan plc (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal place of business in New Jersey and was formerly known as WATSON PHARMA, INC. ACTAVIS LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey, and no members of ACTAVIS LLC are citizens of Arkansas. Each of these Defendants is owned by Allergan plc, which uses them to market and sell its drugs in the United States. Allergan Plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis Plc acquired Allergan plc in March 2015, and the combined company changed its name to Allergan plc in January 2013. Before that, WATSON PHARMACEUTICALS, INC. acquired ACTAVIS, INC. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis plc in October 2013. Upon information and belief, Allergan plc exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. (Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as "Actavis.") Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions

of Duragesic and Opana, in the U.S. and Arkansas. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

C. Distributor Defendants

23. AMERISOURCEBERGEN DRUG CORPORATION, is a Delaware corporation with a principal place of business in Chesterbrook, Pennsylvania, and distributes opioids within Arkansas.

24. CARDINAL HEALTH, INC. is an Ohio corporation with its principal office located in Dublin, Ohio, and distributes opioids within Arkansas.

25. McKESSON CORPORATION, is a Delaware corporation that has its principal place of business located in San Francisco, California, and distributes opioids within Arkansas.

26. Plaintiffs have named three (3) wholesale distributors which dominate 85% of the market share for the distribution of prescription opioids. The "Big 3" are Fortune 500 corporations listed on the New York Stock Exchange whose principal business is the nationwide wholesale distribution of prescription drugs. Each has been investigated and/or fined by the DEA for the failure to report suspicious orders. Plaintiffs allege that each has engaged in unlawful conduct which resulted in the diversion of prescription opioids into our community and that discovery will likely reveal others who likewise engaged in unlawful conduct.

IV. FACTUAL ALLEGATIONS

27. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, pain relating to recovery from surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other

side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

28. To take advantage of the lucrative market for chronic pain patients, each Defendant developed a well-funded marketing scheme based on deception. Each Defendant used both direct marketing and unbranded advertising disseminated by seemingly independent third parties to spread false and deceptive statements about the risks and benefits of long-term opioid use – statements that benefited not only themselves and the third-parties who gained legitimacy when Manufacturer Defendants repeated those statements, but also other Manufacturer Defendants and opioid manufacturers. Yet these statements were not only unsupported by or contrary to the scientific evidence, they were also contrary to pronouncements by and guidance from the FDA and CDC based on that evidence. They also targeted susceptible prescribers and vulnerable patient populations.

A. Manufacturer Defendants Used Multiple Avenues To Disseminate Their False And Deceptive Statements About Opioids.

29. Manufacturer Defendants spread their false and deceptive statements by marketing their branded opioids directly to doctors and patients in Arkansas. Manufacturer Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the State.

30. Manufacturer Defendants spread and continue to spread their false and deceptive statements through direct marketing of their branded opioids.

31. Manufacturer Defendants' direct marketing of opioids generally proceeded on two tracks. First, each Defendant conducted and continues to conduct advertising campaigns touting the purported benefits of their branded drugs. For example, Manufacturer Defendants spent more

than $14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. This amount included $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo.

32. A number of Manufacturer Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker and chef, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Purdue also ran a series of ads, called "Pain vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively. Endo and Purdue agreed in late 2015 and 2016 to halt these misleading representations in New York, but they may continue to disseminate them in Arkansas.

33. Second, each Defendant promoted the use of opioids for chronic pain through "detailers" – sales representatives who visited individual doctors and medical staff in their offices – and small-group speaker programs. Manufacturer Defendants have not corrected this misinformation. Instead, each Defendant devoted and continues to devote massive resources to direct sales contacts with doctors. In 2014 alone, Manufacturer Defendants spent $168 million on detailing branded opioids to doctors. This amount is twice as much as Manufacturer Defendants spent on detailing in 2000. The amount includes $108 million spent by Purdue, $34 million by Janssen, $13 million by Cephalon, $10 million by Endo, and $2 million by Actavis.

34. Manufacturer Defendants' detailers have been reprimanded for their deceptive promotions. A July 2010 "Dear Doctor" letter mandated by the FDA required Actavis to

acknowledge to the doctors to whom it marketed its drugs that "[b]etween June 2009 and February 2010, Actavis sales representatives distributed . . . promotional materials that . . . omitted and minimized serious risks associated with [Kadian]," including the risk of "[m]isuse, [a]buse, and [d]iversion of [o]pioids" and, specifically, the risk that "[o]pioid[s] have the potential for being abused and are sought by drug abusers and people with addiction disorders and are subject to criminal diversion."

35. Manufacturer Defendants also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by Manufacturer Defendants. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Manufacturer Defendants. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Manufacturer Defendants' prior misrepresentations about the risks and benefits of opioids.

36. Manufacturer Defendants' detailing to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face detailing having the greatest influence. Even without such studies, Manufacturer Defendants purchase, manipulate and analyze some of the most sophisticated data available in any industry, data available from IMS Health Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by individual doctor, which in turn allows them to target, tailor, and monitor the impact of their core messages. Thus, Manufacturer Defendants know their detailing to doctors is effective.

37. Manufacturer Defendants employed the same marketing plans and strategies and deployed the same messages in Arkansas as they did nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Manufacturer Defendants' messages are accurately and consistently delivered across marketing channels – including detailing visits, speaker events, and advertising – and in each sales territory. Manufacturer Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

38. Manufacturer Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. Manufacturer Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

39. Manufacturer Defendants used a diverse group of seemingly independent third parties to spread false and deceptive statements about the risks and benefits of opioids.

40. Manufacturer Defendants also deceptively marketed opioids in Arkansas through unbranded advertising – i.e., advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Manufacturer Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as Manufacturer Defendants controlled the distribution of their "core

messages" via their own detailers and speaker programs, Manufacturer Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, CMEs, and medical conferences and seminars. To this end, Manufacturer Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

41. Manufacturer Defendants also marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. Manufacturer Defendants also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, Manufacturer Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of longterm opioid use for chronic pain.

42. Manufacturer Defendants' deceptive unbranded marketing often contradicted what they said in their branded materials reviewed by the FDA.

1. Key Opinion Leaders ("KOLs")

43. Manufacturer Defendants also spoke through a small circle of doctors who, upon information and belief, were selected, funded, and elevated by Manufacturer Defendants because their public positions supported the use of opioids to treat chronic pain. These doctors became known as "key opinion leaders" or "KOLs."

44. Manufacturer Defendants paid KOLs to serve as consultants or on their advisory boards and to give talks or present CMEs, and their support helped these KOLs become respected industry experts. As they rose to prominence, these KOLs touted the benefits of opioids to treat chronic pain, repaying Manufacturer Defendants by advancing their marketing goals. KOLs'

professional reputations became dependent on continuing to promote a pro-opioid message, even in activities that were not directly funded by Manufacturer Defendants.

45. KOLs have written, consulted on, edited, and lent their names to books and articles, and given speeches and CMEs supportive of chronic opioid therapy. Manufacturer Defendants created opportunities for KOLs to participate in research studies Manufacturer Defendants suggested or chose and then cited and promoted favorable studies or articles by their KOLs. By contrast, Manufacturer Defendants did not support, acknowledge, or disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

46. Manufacturer Defendants' KOLs also served on committees that developed treatment guidelines that strongly encourage the use of opioids to treat chronic pain, and on the boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs. Manufacturer Defendants were able to direct and exert control over each of these activities through their KOLs. The 2016 CDC Guideline recognizes that treatment guidelines can "change prescribing practices."

47. Pro-opioid doctors are one of the most important avenues that Manufacturer Defendants use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. Manufacturer Defendants know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with Purdue that the Purdue website In the Face of Pain failed to disclose that doctors who provided testimonials on the site were paid by Purdue and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

48. Thus, even though some of Manufacturer Defendants' KOLs have recently moderated or conceded the lack of evidence for many of the claims they made, those admissions did not reverse the effect of the false and deceptive statements that continue to appear nationwide and throughout the State of Arkansas in Manufacturer Defendants' own marketing as well as treatment guidelines, CMEs and other seminars, scientific articles and research, and other publications available in paper or online.

49. Manufacturer Defendants utilized many KOLs, including many of the same ones. Two of the most prominent are described below.

50. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom Manufacturer Defendants identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue.

51. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS") / American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1997 and again in 2009. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by Manufacturer Defendants.

52. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations. He appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast in Arkansas and across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly

uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted."

53. To his credit, Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist." Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did."

54. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a front group that ardently supports chronic opioid therapy. He is a Senior Editor of Pain Medicine, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Manufacturer Defendants (including nearly $2 million from Cephalon).

55. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice's Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses.

56. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue.

57. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, Managing Patient's Opioid Use: Balancing the Need and the Risk. Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach Arkansas doctors.

58. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to increase a patient's dose of opioids. As he and his co-author wrote in a book entitled Avoiding Opioid Abuse While Managing Pain (2007), a book that is still available online, when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response." Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."

2. Front Groups

59. Manufacturer Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of

chronic pain. Under the direction and control of Manufacturer Defendants, these "Front Groups" generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. They also assisted Manufacturer Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Manufacturer Defendants.

60. These Front Groups depended on Manufacturer Defendants for funding and, in some cases, for survival. Manufacturer Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, Manufacturer Defendants made sure that the Groups would generate only the messages Manufacturer Defendants wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

61. Manufacturer Defendants Cephalon, Endo, Janssen, and Purdue utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF") and Pain & Policy Studies Group ("PPSG").

62. The most prominent of Manufacturer Defendants' Front Groups was APF, which received more than $10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. Endo alone provided more than half that funding; Purdue was next, at $1.7 million.

63. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning soldiers. APF also engaged in a significant multimedia campaign – through radio, television and the internet – to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach Arkansas' citizens.

64. In addition to Perry Fine (a KOL from the University of Utah who received funding from Janssen, Cephalon, Endo, and Purdue) Russell Portenoy, and Scott Fishman (a KOL from the University of California, Davis who authored Responsible Opioid Prescribing, a publication sponsored by Cephalon and Purdue), all of whom served on APF's Board and reviewed its publications, another board member, Lisa Weiss, was an employee of a public relations firm that worked for both Purdue and APF.

65. In 2009 and 2010, more than 80% of APF's operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about $2.3 million from industry sources out of total income of about $2.85 million in 2009; its budget for 2010 projected receipts of roughly $2.9 million from drug companies, out of total income of about $3.5 million. By 2011, APF was entirely dependent on incoming grants from Manufacturer Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. As one of its board members, Russell Portenoy, explained, the lack of funding diversity was one of the biggest problems at APF.

66. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid

prescribing, and thus the profitability of its sponsors. It was often called upon to provide "patient representatives" for Manufacturer Defendants' promotional activities, including for Purdue's Partners Against Pain and Janssen's Let's Talk Pain. APF functioned largely as an advocate for the interests of Manufacturer Defendants, not patients. Indeed, as early as 2001, Purdue told APF that the basis of a grant was Purdue's desire to "strategically align its investments in nonprofit organizations that share [its] business interests."

67. In practice, APF operated in close collaboration with opioid makers. On several occasions, representatives of the drug companies, often at informal meetings at Front Group conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

68. APF assisted in other marketing projects for drug companies. One project funded by another drug company – APF Reporter's Guide: Covering Pain and Its Management (2009) – recycled text that was originally created as part of the company's training document.

69. The same drug company made general grants, but even then it directed how APF used them. In response to an APF request for funding to address a potentially damaging state Medicaid decision related to pain medications generally, the company representative responded, "I provided an advocacy grant to APF this year – this would be a very good issue on which to use some of that. How does that work?"

70. The close relationship between APF and the drug company was not unique, but mirrors relationships between APF and Manufacturer Defendants. APF's clear lack of independence – in its finances, management, and mission – and its willingness to allow

Manufacturer Defendants to control its activities and messages support an inference that each Defendant that worked with it was able to exercise editorial control over its publications.

71. Indeed, the U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF's credibility as an objective and neutral third party, and Manufacturer Defendants stopped funding it. Within days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."

72. The American Academy of Pain Medicine, with the assistance, prompting, involvement, and funding of Manufacturer Defendants, issued treatment guidelines and sponsored and hosted medical education programs essential to Manufacturer Defendants' deceptive marketing of chronic opioid therapy.

73. AAPM received over $2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid $25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM's marquee event – its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Manufacturer Defendants Endo, Purdue, Cephalon and Actavis were members of the council and presented deceptive programs to doctors who attended this annual event.

74. AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids – 37 out of roughly 40 at one conference alone. AAPM's presidents have included top industry-supported KOLs Perry Fine, Russell Portenoy, and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation. Another past AAPM president, Dr. Scott Fishman, stated that he would place the organization "at the forefront" of teaching that "the risks of addiction are . . . small and can be managed."

75. AAPM's staff understood they and their industry funders were engaged in a common task. Manufacturer Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

76. In addition, treatment guidelines have been particularly important in securing acceptance for chronic opioid therapy. They are relied upon by doctors, especially the general practitioners and family doctors targeted by Manufacturer Defendants, who are neither experts nor trained in the treatment of chronic pain. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discussed treatment guidelines with doctors during individual sales visits.

77. In 1997, AAPM and the American Pain Society jointly issued a consensus statement, The Use of Opioids for the Treatment of Chronic Pain, which endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The co-author of the statement, Dr. Haddox, was at the time a paid speaker for Purdue. Dr.

Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and was taken down from AAPM's website only after a doctor complained, though it lingers on the internet elsewhere.

78. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue.

79. The 2009 Guidelines promote opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Manufacturer Defendants, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians, but also the body of scientific evidence on opioids; the Guidelines have been cited 732 times in academic literature, were disseminated in Arkansas during the relevant time period, are still available online, and were reprinted in the Journal of Pain.

80. Manufacturer Defendants widely referenced and promoted the 2009 Guidelines without disclosing the acknowledged lack of evidence to support them.

81. Manufacturer Defendants worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Manufacturer Defendants combined their efforts through the Pain Care Forum (PCF), which began

in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Cephalon, Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from Manufacturer Defendants. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably negative and did not require mandatory participation by prescribers, which Manufacturer Defendants determined would reduce prescribing.

B. Manufacturer Defendants' Marketing Scheme Misrepresented The Risks And Benefits Of Opioids.

82. To convince doctors and patients in Arkansas that opioids can and should be used to treat chronic pain, Manufacturer Defendants had to convince them that long-term opioid use is both safe and helpful. Knowing that they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, Manufacturer Defendants made claims that were not supported by or were contrary to the scientific evidence. Even though pronouncements by and guidance from the FDA and the CDC based on that evidence confirm that their claims were false and deceptive, Manufacturer Defendants have not corrected them, or instructed their KOLs or Front Groups to correct them, and continue to spread them today.

1. Manufacturer Defendants falsely trivialized or failed to disclose the known risks of long-term opioid use.

83. To convince doctors and patients that opioids are safe, Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations – which are described below – reinforced each other and created the dangerously misleading impression that: (1) starting patients on opioids was low-risk because most patients would not become addicted, and because those who were at greatest risk of

addiction could be readily identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Manufacturer Defendants have not only failed to correct these misrepresentations, they continue to make them today.

84. First, Manufacturer Defendants falsely claimed that the risk of addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to disclose the greater risk of addiction with prolonged use of opioids. Some illustrative examples of these false and deceptive claims are described below:

a. Actavis's predecessor caused a patient education brochure to be distributed in 2007 that claimed opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond.

b. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.

c. Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."

d. Endo distributed a pamphlet with the Endo logo entitled Living with Someone with Chronic Pain, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website www.opana.com.

e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

f. Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are "overestimated."

g. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management – which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction[]." This publication is still available online.

h. Detailers for Purdue, Endo, Janssen, and Cephalon in Arkansas minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above.

85. These claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC Guideline endorsed by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])." The Guideline points out that "[o]pioid pain medication

use presents serious risks, including . . . opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder."

86. The FDA further exposed the falsity of Manufacturer Defendants' claims about the low risk of addiction when it announced changes to the labels for ER/LA opioids in 2013 and for IR opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."

87. The warnings on Manufacturer Defendants' own FDA-approved drug labels caution that opioids "expose[] users to risks of addiction, abuse and misuse, which can lead to overdose and death," that the drugs contain "a substance with a high potential for abuse," and that addiction "can occur in patients appropriately prescribed" opioids.

88. The State of New York, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder." Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the State found that Endo

had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. Endo remains free, however, to make those statements in Arkansas.

89. Second, Manufacturer Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of undertreated pain and should be treated by prescribing more opioids. Manufacturer Defendants called this phenomenon "pseudoaddiction" – a term coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, a KOL for Cephalon, Endo, Janssen, and Purdue – and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some illustrative examples of these deceptive claims are described below:

a. Cephalon and Purdue sponsored Responsible Opioid Prescribing (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction. Responsible Opioid Prescribing remains for sale online. The 2012 edition, which also remains available online, continues to teach that pseudoaddiction is real.

b. Janssen sponsored, funded, and edited the Let's Talk Pain website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."

c. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia, which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the

result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

d. Purdue published a pamphlet in 2011 entitled Providing Relief, Preventing Abuse, which described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."

e. Purdue sponsored a CME program entitled Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse. In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.

90. The 2016 CDC Guideline rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid dosages be increased if a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with longer-term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

91. Even one of the Manufacturer Defendants has effectively repudiated the concept of pseudoaddiction. In finding that "[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents," the State of New York, in

its 2016 settlement with Endo, reported that "Endo's Vice President for Pharmacovigilance and Risk Management testified that he was not aware of any research validating the 'pseudoaddiction' concept" and acknowledged the difficulty in distinguishing "between addiction and 'pseudoaddiction.'" Consistent with this, Endo agreed not to "use the term 'pseudoaddiction' in any training or marketing" in New York. Endo, however, remains free to do so in Arkansas.

92. Third, Manufacturer Defendants falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because Manufacturer Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Manufacturer Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Some illustrative examples of these deceptive claims are described below:

a. Endo paid for a 2007 supplement in the Journal of Family Practice written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled Pain Management Dilemmas in Primary Care: Use of Opioids, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

b. Purdue sponsored a 2011 webinar, Managing Patient's Opioid Use: Balancing the Need and Risk, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

c. As recently as 2015, Purdue has represented in scientific conferences that "bad apple" patients – and not opioids – are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

93. Once again, the 2016 CDC Guideline confirms the falsity of these misrepresentations. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies – such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse – "for improving outcomes related to overdose, addiction, abuse, or misuse." As a result, the Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

94. Fourth, to underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Manufacturer Defendants falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, and failed to disclose the increased difficulty of stopping opioids after long-term use.

95. For example, a CME sponsored by Endo, entitled Persistent Pain in the Older Adult, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days. And Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which claimed that "[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation" without mentioning any hardships that might occur.

96. Manufacturer Defendants deceptively minimized the significant symptoms of opioid withdrawal – which, as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction – and grossly understated the difficulty of tapering, particularly after long-term opioid use. Yet the 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms," because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days." The Guideline further states that "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence" and highlights the difficulties, including the need to carefully identify "a taper slow enough to minimize symptoms and signs of opioid withdrawal" and to "pause[] and restart[]" tapers depending on the patient's response. The CDC also acknowledges the lack of any "high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued."

97. Fifth, Manufacturer Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Manufacturer Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. Some illustrative examples are described below:

a. Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require

a dose adjustment to get the right amount of pain relief. This is not addiction." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond.

b. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. This guide is still available for sale online.

c. Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

d. Endo distributed a pamphlet edited by a KOL entitled Understanding Your Pain: Taking Oral Opioid Analgesics, which was available during the time period of this Complaint on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."

e. Janssen sponsored a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

f. Purdue's In the Face of Pain website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

g. Purdue sponsored APF's A Policymaker's Guide to Understanding Pain & Its Management, which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online.

h. Purdue sponsored a CME entitled Overview of Management Options that is still available for CME credit. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, the "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders,"19 challenging the correlation between opioid dosage and overdose.

98. These claims conflict with the scientific evidence, as confirmed by the FDA and CDC. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC also states that "there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages." That is why the CDC advises doctors to "avoid increasing dosages" above 90 morphine milligram equivalents per day.

99. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

100. Finally, Manufacturer Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can curb addiction and abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive.

101. More specifically, Manufacturer Defendants have made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that there was no evidence Endo's design "would provide a reduction in oral, intranasal or intravenous abuse." Moreover, Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.

102. In a 2016 settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The State found those statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER. Similarly, the 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies – even when they work – "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes."

103. These numerous, longstanding misrepresentations of the risks of long-term opioid use spread by Manufacturer Defendants successfully convinced doctors and patients to discount those risks.

2. Manufacturer Defendants grossly overstated the benefits of chronic opioid therapy.

104. To convince doctors and patients that opioids should be used to treat chronic pain, Manufacturer Defendants also had to persuade them that there was a significant upside to long-term opioid use. But as the 2016 CDC Guideline makes clear, there is "insufficient evidence to determine the long-term benefits of opioid therapy for chronic pain." In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials ≤ 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks." Despite this, Manufacturer Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have Manufacturer Defendants failed to correct these false and deceptive claims, they continue to make them today.

105. For example, Manufacturer Defendants falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples are described below:

a. Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

b. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.

c. Janssen sponsored and edited a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009) – which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.

d. Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.

e. Responsible Opioid Prescribing (2007), sponsored and distributed by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online.

f. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in 2012.

g. Endo's NIPC website painknowledge.com claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life

(as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site.

h. Endo was the sole sponsor, through NIPC, of a series of CMEs titled Persistent Pain in the Older Patient, which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive

symptoms and cognitive functioning." The CME was disseminated via webcast.

i. Janssen sponsored, funded, and edited a website, Let's Talk Pain, in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function." This video is still available today on YouTube.

j. Purdue sponsored the development and distribution of APF's A Policymaker's Guide to Understanding Pain & Its Management, which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients." The Policymaker's Guide was originally published in 2011 and is still available online today.

k. Purdue's, Cephalon's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

106. These claims find no support in the scientific literature. The FDA and other federal agencies have made this clear for years. Most recently, the 2016 CDC Guideline approved by the FDA concluded that "there is no good evidence that opioids improve pain or function with long-term use, and . . . complete relief of pain is unlikely." (Emphasis added.) The CDC reinforced this conclusion throughout its 2016 Guideline:

- "No evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later . . ."
- "Although opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy."
- "[E]vidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

107. The CDC also noted that the risks of addiction and death "can cause distress and inability to fulfill major role obligations." As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

108. The 2016 CDC Guideline was not the first time a federal agency repudiated Manufacturer Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis, in response to its advertising, that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life." And in 2008, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

109. Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.

110. In addition, Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all times relevant to this action. According to Purdue's own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial number" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

111. Purdue's competitors were aware of this problem. For example, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Indeed, Purdue's sales representatives continue to tell Arkansas doctors that OxyContin lasts a full 12 hours.

112. Front Groups supported by Purdue likewise echoed these representations. For example, in an amicus brief submitted to the Supreme Court of Arkansas by the American Pain Foundation, the National Foundation for the Treatment of Pain and the Arkansas Pain Initiative in support of Purdue, those amici represented:

> Oxycontin is particularly useful for sustained long-term pain because it comes in higher, compact pills with a slow release coating. OxyContin pills can work for 12 hours. This makes it easier for patients to comply with dosing requirements without experiencing a roller-coaster of pain relief followed quickly by pain renewal that can occur with shorter acting medications. It also helps the patient sleeps though the night, which is often impossible with short-acting medications. For many of those serviced by Pain Care Amici, Oxycontin has been a miracle medication.

3. Manufacturer Defendants also engaged in other unlawful, unfair, and fraudulent misconduct.

113. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse – which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

114. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

a. Cephalon paid to have a CME it sponsored, Opioid-Based Management of Persistent and Breakthrough Pain, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

b. Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

c. In December 2011, Cephalon widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to Anesthesiology News, Clinical Oncology News, and Pain Medicine News – three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

115. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

116. Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue's sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin – the same OxyContin that Purdue had promoted as less addictive – in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the Los Angeles Times, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described internally as "an organized drug ring." In doing so, Purdue protected its own profits at the expense of public health and safety.

117. The State of New York's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. Yet, on information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers.

118. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State

of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

C. Manufacturer Defendants Targeted Susceptible Prescribers And Vulnerable Patient Populations.

119. As a part of their deceptive marketing scheme, Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including Arkansas. For example, Manufacturer Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept Manufacturer Defendants' misrepresentations.

120. Manufacturer Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. Manufacturer Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence shows that elderly patients taking opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and increased vulnerability to adverse drug effects and interactions. The Guideline therefore concludes that there are "special risks of long-term opioid use for elderly patients" and recommends that doctors use "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

D. Although Manufacturer Defendants Knew That Their Marketing Of Opioids Was False And Deceptive, They Fraudulently Concealed Their Misconduct.

121. Manufacturer Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Manufacturer Defendants of this, and Manufacturer Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths – all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of Manufacturer Defendants' misrepresentations, and Endo and Purdue have recently entered agreements prohibiting them from making some of the same misrepresentations described in this Complaint in New York.

122. Moreover, at all times relevant to this Complaint, Manufacturer Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, Manufacturer Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. Manufacturer Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of Manufacturer Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain.

123. Manufacturer Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. Manufacturer Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, painknowledge.org, which is run by the NIPC, did not disclose Endo's involvement. Other Manufacturer Defendants, such as Purdue and Janssen, ran similar websites that masked their own direct role.

124. Finally, Manufacturer Defendants manipulated their promotional materials and the scientific literature to make it appear that these items were accurate, truthful, and supported by objective evidence when they were not. Manufacturer Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for Manufacturer Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by Plaintiffs.

125. Thus, Manufacturer Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the claims that Plaintiffs now assert. Plaintiffs did not know of the existence or scope of Manufacturer Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

E. By Increasing Opioid Prescriptions And Use, Manufacturer Defendants' Deceptive Marketing Scheme Has Fueled The Opioid Epidemic And Devastated Arkansas Communities.

126. Manufacturer Defendants' misrepresentations deceived doctors and patients about the risks and benefits of long-term opioid use. Studies also reveal that many doctors and patients

are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive.

127. Manufacturer Defendants' deceptive marketing scheme caused and continues to cause doctors in Arkansas to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent Manufacturer Defendants' deceptive marketing scheme, these doctors would not have prescribed as many opioids. Manufacturer Defendants' deceptive marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent Manufacturer Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

128. Manufacturer Defendants' deceptive marketing has caused and continues to cause the prescribing and use of opioids to explode. Indeed, this dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in Manufacturer Defendants' spending on their deceptive marketing scheme. Manufacturer Defendants' spending on opioid marketing totaled approximately $91 million in 2000. By 2011, that spending had tripled to $288 million.

129. The escalating number of opioid prescriptions written by doctors who were deceived by Manufacturer Defendants' deceptive marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S. and Arkansas. In August 2016, then-U.S. Surgeon General Vivek Murthy published an open letter to be sent to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain,

and the "devastating" results that followed, had "coincided with heavy marketing to doctors . . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when prescribed for legitimate pain."

130. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In a 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving prescription opioids for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

131. Contrary to Manufacturer Defendants' misrepresentations, most opioid addiction begins with legitimately prescribed opioids, and therefore could have been prevented had Manufacturer Defendants' representations to prescribers been truthful. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers or the internet. Numerous doctors and substance abuse counselors note that many of their patients who misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors' prescribing habits have played in the opioid epidemic.

132. As the FDA observed in 2016, the opioid epidemic is getting worse, not better. Opioids are by far the most commonly prescribed class of substances in Arkansas. When compared to previous drug overdose epidemics in Arkansas, the current prescription drug epidemic is responsible for considerably more deaths, and the epidemic will continue unabated absent relief from the Court.

133. Manufacturer Defendants' deceptive marketing scheme has also had a significant detrimental impact on children in Arkansas in a number of ways. The overprescribing of opioids

for chronic pain has made the drugs more accessible to school-aged children, who come into contact with opioids after they have been prescribed to friends or relatives in the same household. Furthermore, children with parents addicted to drugs tend to stay in foster care longer, and they often enter the system having experienced significant trauma, which makes these cases more expensive to deal with. Although the foster care system in Arkansas is managed by the State, Plaintiffs bear many of the additional costs caused by Defendants' actions.

134. The overprescribing of opioids for chronic pain caused by Manufacturer Defendants' deceptive marketing scheme has also resulted in a dramatic rise in the number of infants in Arkansas who are born addicted to opioids due to prenatal exposure and suffer from neonatal abstinence syndrome. These infants face painful withdrawal and may suffer long-term neurologic and cognitive impacts. Babies with NAS typically require extensive hospital stays as they withdraw.

135. Opioid addiction is now the primary reason that Arkansas' citizens seek substance abuse treatment. The number of emergency medical services ("EMS") runs for suspected opioid-related overdose has also increased. The costs associated with the increase in medical treatments is borne in part by Plaintiffs.

136. Manufacturer Defendants' creation, through false and deceptive advertising and other unlawful and unfair conduct, of a virtually limitless opioid market has significantly harmed communities throughout Arkansas. Manufacturer Defendants' success in extending the market for opioids to new patients and chronic pain conditions has created an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and injury. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through doctors' prescriptions.

137. Law enforcement agencies have increasingly associated prescription drug abuse with violent and property crimes. Despite strict federal regulation of prescription drugs, local law enforcement agencies are faced with increasing diversion from legitimate sources for illicit purposes, including: doctor shopping, forged prescriptions, falsified pharmacy records, and employees who steal from their place of employment. The opioid epidemic has prompted a growing trend of crimes against pharmacies including robbery and burglary. In fact, a 2005 study by The Center on Addiction and Substance Abuse at Columbia University revealed that, by that time, 20.9% of pharmacies nationwide had stopped stocking certain medications such as OxyContin and Percocet, in order to protect themselves from robbery. This ongoing diversion of prescription narcotics creates a lucrative marketplace

138. The costs and consequences of opioid addiction are staggering. Prescription opioid misuse, abuse and overdose have an enormous impact on the health and safety of individuals as well as communities at large, as the consequences of this epidemic reach far beyond the individual who is addicted. Some of the repercussions for individuals include job loss, loss of custody of children, physical and mental health problems, homelessness and incarceration. This results in instability in communities often already in economic crisis and contributes to increased demand on community services such as hospitals, courts, child services, treatment centers and law enforcement.

139. Manufacturer Defendants knew and should have known about these harms that their deceptive marketing has caused. Manufacturer Defendants closely monitored their sales and the habits of prescribing doctors. Their sales representatives, who visited doctors and attended CMEs, knew which doctors were receiving their messages and how they were responding. Manufacturer Defendants also had access to and watched carefully government and other data that tracked the

explosive rise in opioid use, addiction, injury, and death. They knew – and, indeed, intended – that their misrepresentations would persuade doctors to prescribe and patients to use their opioids for chronic pain.

140. Manufacturer Defendants' actions are not permitted nor excused by the fact that their drug labels (with the exception of the Actiq/Fentora labels) may have allowed or did not exclude the use of opioids for chronic pain. FDA approval of opioids for certain uses did not give Manufacturer Defendants license to misrepresent the risks and benefits of opioids. Indeed, Manufacturer Defendants' misrepresentations were directly contrary to pronouncements by and guidance from the FDA based on the medical evidence and their own labels.

141. Nor is Manufacturer Defendants' causal role broken by the involvement of doctors. Manufacturer Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Manufacturer Defendants also were able to harness and hijack what doctors wanted to believe – namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

F. Distributor Defendants Likewise Breached Their Duties to Plaintiffs

142. The supply chain for prescription opioids begins with the manufacture and packaging of the pills. The manufacturers then transfer the pills to distribution companies, including the Defendants Cardinal, McKesson, and AmerisourceBergen, which together account for 85 to 90 percent of all revenues from drug distribution in the United States, estimated to be at $378.4 billion in 2015. The distributors then supply opioids to hospitals, pharmacies, doctors, and other healthcare providers, which then dispense the drugs to patients.

143. Each participant in the supply chain shares the responsibility for controlling the availability of prescriptions opioids. Opioid "diversion" occurs whenever the supply chain of prescription opioids is broken, and the drugs are transferred from a legitimate channel of distribution or use, to an illegitimate channel of distribution or use.

144. Athe wholesale level of distribution, diversion occurs whenever distributors allow opioids to be lost or stolen in transit, or when distributors fill suspicious orders of opioids from retailers or prescribers. Suspicious orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency.

145. Opioid diversion occurs in the United States at an alarming rate. In recent years, the number of people who take prescription opioids for non-medical purposes is greater than the number of people who use cocaine, heroin, hallucinogens, and inhalants combined.

146. Like all people, Distributors Defendants have a duty to exercise reasonable care under the circumstances. This involves a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct-and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another-is under a duty to exercise reasonable care to prevent the threatened harm.

147. In addition to having common law duties, the Distributor Defendants are governed by the statutory requirements of the Controlled Substances Act ("CSA"), 21 U.S.C. § 801 *et seq.* and its implementing regulations. These requirements were enacted to protect society from the harms of drug diversion. The Distributor Defendants' violation of these requirements shows that they failed to meet the relevant standard of conduct that society expects from them.

148. By violating the CSA, the Distributor Defendants arc also liable to Plaintiffs under Arkansas' Deceptive Trade Practices Act, which specifically makes it a civil offense to violate federal statutes affecting or impacting chattels bought for medical purposes.

149. The CSA creates a legal framework for the distribution and dispensing of controlled substances. Congress passed the CSA partly out of a concern about "the widespread diversion of [controlled substances] out of legitimate channels into the illegal market." *See* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; 4572.

150. Accordingly, the CSA acts as a system of checks and balances from the manufacturing level through delivery of the pharmaceutical drug to the patient or ultimate user. Every person or entity who manufactures, distributes, or dispenses opioids must obtain a registration with the DEA. Registrants at every level of the supply chain must fulfill their obligations under the CSA, otherwise controlled substances move from the licit to the illicit marketplace, and there is great potential for harm to the general public.

151. All opioid distributors are required to maintain effective controls against opioid diversion. They are also required to create and use a system to identify and report downstream suspicious orders of controlled substances to law enforcement. Suspicious orders include orders of unusual size, orders deviating substantially from the normal pattern, and orders of unusual frequency. To comply with these requirements, distributors must know their customers, report suspicious orders, conduct due diligence, and terminate orders if there are indications of diversion.

152. To prevent unauthorized users from obtaining opioids, the CSA creates a distribution monitoring system for controlled substances. At the heart of this system are registration and tracking requirements imposed upon anyone authorized to handle controlled substances. The DEA's Automation of Reports and Consolidation Orders System ("ARCOS") is

an automated drug reporting system which monitors the flow of Schedule II controlled substances from their point of manufacture through commercial distribution channels to point of sale. ARCOS accumulates data on distributors' controlled substances acquisition/distribution transactions, which are then summarized into reports used by the DEA to identify any diversion of controlled substances into illicit channels of distribution. Each person or entity that is registered to distribute ARCOS Reportable controlled substances must report acquisition and distribution transactions to the DEA.

153. Acquisition and distribution transaction reports must provide data on each acquisition to inventory (identifying whether it is, e.g., by purchase or transfer, return from a customer, or supply by the Federal Government) and each reduction from inventory (identifying whether it is, e.g., by sale or transfer, theft, destruction or seizure by Government agencies) for each ARCOS Reportable controlled substance. See 21 U.S.C. § 827(d)(1); 21 C.F.R. §§ 1304.33(e), (d). Inventory that has been lost or stolen must also be reported separately to the DEA within one business day of discovery of such loss or theft.

154. In addition to filing acquisition/distribution transaction reports, each registrant is required to maintain on a current basis a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of. See 21 U.S.C. §§ 827(a)(3), 1304.21(a), 1304.22(b). It is unlawful for any person to negligently fail to abide by the recordkeeping and reporting requirements.

155. In order to maintain registration, distributors must also maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific and industrial channels. When determining if a distributor has provided effective controls, the DEA Administrator refers to the security requirements set forth in §§ 1301.72-1301.76 as standards for

the physical security controls and operating procedures necessary to prevent diversion. See 21 CFR § 1301.71.

G. Distributor Defendants Knew Or Should Have Known They Were Facilitating Widespread Opioid Diversion.

156. The problem of opioid diversion in the supply chain has been widely publicized for years. Numerous publications, studies, federal agencies, and professional organizations have highlighted the epidemic rate of opioid abuse and overdose rates in communities in Arkansas, as well as throughout the United States.

157. To combat the problem of opioid diversion, the DEA has provided guidance to distributors on the requirements of suspicious order reporting in numerous venues, publications, documents, and final agency actions.

158. Since 2006, the DEA has conducted one-on-one briefings with distributors regarding downstream customer sales, their due diligence responsibilities, and their legal and regulatory responsibilities (including the responsibility to know their customers and report suspicious orders to the DEA). The DEA provided distributors with data on controlled substance distribution patterns and trends, including data on the volume of orders, frequency of orders, and percentage of controlled vs. non-controlled purchases. The distributors were also given case studies, legal findings against other registrants, and ARCOS profiles of their customers whose previous purchases may have reflected suspicious ordering patterns. The DEA pointed out the "red flags" distributors should look for in order to identify potential diversion. This initiative was created to help distributors understand their duties with respect to diversion control.

159. Since 2007, the DEA has hosted at least five conferences to provide registrants with updated information about diversion trends and regulatory changes that affect the drug supply chain, the distributor initiative, and suspicious order reporting. All of the major distributors

attended at least one of these conferences. The conferences allowed the registrants to ask questions and raise concerns. Registrants could also request clarification on DEA policies, procedures, and interpretations of the CSA and implementing regulations.

160. Since 2008, the DEA has participated in numerous meetings and events with the legacy Healthcare Distribution Management Association (HDMA), now known as the Healthcare Distribution Alliance (HAD), an industry trade association for wholesalers and distributors. DEA representatives have provided guidance to the association concerning suspicious order monitoring, and the association has published guidance documents for its members on suspicious order monitoring, reporting requirements, and the diversion of controlled substances.

161. On September 27, 2006 and again on December 27, 2007, the DEA Office of Diversion Control sent letters to all registered distributors providing guidance on suspicious order monitoring of controlled substances and the responsibilities and obligations of the registrant to conduct due diligence on controlled substance customers as part of a program to maintain effective controls against diversion.

162. The September 27, 2006 letter reminded registrants that they are required by law to exercise due diligence to avoid filling orders that may be diverted into the illicit market. It explained that as part of the legal obligation to maintain effective controls against diversion, the distributor is required to exercise due care in confirming the legitimacy of all orders prior to filling. It also described circumstances that could be indicative of diversion including ordering excessive quantities of a limited variety of controlled substances while ordering few if any other drugs; disproportionate ratio of ordering controlled substances to non-controlled prescription drugs; the ordering of excessive quantities of a limited variety of controlled substances in combination with lifestyle drugs; and ordering the same controlled substance from multiple distributors. The letter

went on to describe what questions should be answered by a customer when attempting to make a determination if the order is indeed suspicious.

163. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to DEA registrants providing guidance and reinforcing the legal requirements outlined in the September 2006 correspondence. The letter reminded registrants that suspicious orders must be reported when discovered and monthly transaction reports of excessive purchases did not meet the regulatory criteria for suspicious order reporting. The letter also advised registrants that they must perform an independent analysis of a suspicious order prior to the sale to determine if the controlled substances would likely be diverted, and that filing a suspicious order and then completing the sale does not absolve the registrant from legal responsibility. Finally, the letter directed the registrant community to review a recent DEA action called Southwood Pharmaceuticals, Inc., 72 FR 36487 (2007) that addressed criteria in determining suspicious orders and their obligation to maintain effective controls against diversion.

164. The Distributor Defendants were on notice that their own industry group, the Healthcare Distribution Management Association, published Industry Compliance Guidelines titled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances" that stressed the critical role of each member of the supply chain in distributing controlled substances.

165. These industry guidelines further provided: "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."

166. Opioid distributors have themselves recognized the magnitude of the problem and, at least rhetorically, their legal responsibilities to prevent diversion. They have made statements assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.

167. For example, a Cardinal executive recently claimed that it uses "advanced analytics" to monitor its supply chain; Cardinal assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

168. McKesson has publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders" and claimed it is "deeply passionate about curbing the opioid epidemic in our country."

169. At the very least, these assurances about constantly eliminating criminal activity and curbing the opioid epidemic create a duty for the Distributor Defendants to reasonably follow through.

170. Thus, in addition to the obligations imposed by law, through their own words and actions, the Distributor Defendants have voluntarily undertaken a duty to protect the public at large against diversion from their supply chains, and to curb the opioid epidemic.

171. Despite these kinds of statements, the Distributors Defendants have knowingly or negligently allowed diversion. Their misconduct has resulted in numerous civil fines and other penalties recovered by state and federal agencies-including actions by the DEA related to violations of the Controlled Substances Act.

172. In 2008, Cardinal paid a $34 million penalty to settle allegations about opioid diversion taking place at seven warehouses around the United States. Again in 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states. Just several months ago, in December 2016, a Department of Justice press released announced that, in connection with the CSA violations, the United States "Reaches $34 Million Settlement With Cardinal Health For Civil Penalties Under The Controlled Substances

Act. In connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to a particular pharmacy in Florida that was suspected of opioid diversion. Cardinal did nothing to notify the DEA or cut off the supply of drugs to the suspect pharmacy. Instead, Cardinal's opioid shipments to the pharmacy increased-to almost 2 million doses of oxycodone in one year, while other comparable pharmacies were receiving approximately 69,000 doses/year.

173. In May 2008, McKesson entered into a settlement agreement with the DEA to settle claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the country, resulting in millions of doses of controlled substances being diverted. McKesson agreed to pay a $13.25 million civil fine. After the 2008 settlement, McKesson was supposed to change its ways and act tougher towards opioid diversion. But it did not do so. It was later revealed that McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from only a single consumer. Again in 2015, McKesson found itself in the middle of allegations concerning its "suspicious order reporting practices for controlled substances." In early 2017 it was reported that McKesson agreed to pay $150 million to the government to settle certain opioid diversion claims that it allowed drug diversion at 12 distribution centers in 11 states.

174. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies. Again in 2012, AmerisourceBergen was implicated for failing to protect

against diversion of particular controlled substances into non-medically necessary channels. It has been reported that the U.S. Department of Justice has subpoenaed AmerisourceBergen for documents in connection with a grand jury proceeding seeking information on the company's "program for controlling and monitoring diversion of controlled substances into channels other than for legitimate medical, scientific and industrial purposes.

175. Although distributors have been penalized by law enforcement authorities, these penalties have not changed their conduct. They pay fines as a cost of doing business in an industry which generates billions of dollars in revenue.

H. Distributor Defendants' misconduct has injured and continues to injure Plaintiffs.

176. The Distributor Defendants had the ability and duty to prevent opioid diversion, which presented a known or foreseeable danger of serious injury to Arkansas and Plaintiffs. But they failed to do so.

177. The Distributor Defendants have supplied quantities of prescription opioids in and around Arkansas with the actual or constructive knowledge that the opioids were ultimately being consumed by Arkansas' citizens for non-medical purposes. Many of these shipments should have been stopped or investigated as suspicious orders, but the Distributor Defendants negligently or intentionally failed to do so.

178. Each Distributor Defendant knew or should have known that the amount of opioids that it allowed to flow into Arkansas was far in excess of what could be consumed for medically-necessary purposes in the relevant communities (especially given that each Distributor Defendant knew it was not the only opioid distributor servicing those communities).

179. The Distributor Defendants negligently or intentionally failed to adequately control their supply lines to prevent diversion. A reasonably-prudent distributor of Schedule II controlled

substances would have anticipated the danger of opioid diversion and protected against it by, for example, taking greater care in hiring, training, and supervising employees; providing greater oversight, security, and control of supply channels; looking more closely at the pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in amounts greater than the populations in those areas would warrant; investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers in and around Arkansas; providing information to pharmacies and retailers about opioid diversion; and in general, simply following applicable statutes, regulations, professional standards, and guidance from government agencies.

180. On information and belief, the Distributor Defendants made little to no effort to visit the pharmacies servicing Arkansas to perform due diligence inspections to ensure that the controlled substances the Distributors Defendants had furnished were not being diverted to illegal uses.

181. On information and belief, the compensation the Distributor Defendants provided to certain of their employees was affected, in part, by the volume of their sales of opioids to pharmacies and other facilities servicing Arkansas, thus improperly creating incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid abuse.

182. It was reasonably foreseeable to the Distributor Defendants that their conduct in flooding the market in and around Arkansas with highly-addictive opioids would allow opioids to fall into the hands of children, addicts, criminals, and other unintended users.

183. It is reasonably foreseeable to the Distributor Defendants that, when unintended users gain access to opioids, tragic preventable injuries will result, including addiction, overdoses, and death. It is also reasonably foreseeable many of these injuries will be suffered by Arkansas citizens, and that the costs of these injuries will be shouldered by Plaintiffs.

184. The Distributor Defendants knew or should have known that the opioids being diverted from their supply chains would contribute to the opioid epidemic of Arkansas, and would create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of addiction, demand, and illegal transactions.

185. The Distributor Defendants knew or should have known that a substantial amount of the opioids dispensed in and around Arkansas were being dispensed based on invalid or suspicious prescriptions. It is foreseeable that filling suspicious orders for opioids will cause harm to individual pharmacy customers, third-parties, and Arkansas.

186. The Distributor Defendants were aware of widespread prescription opioid abuse in and around Arkansas, but they nevertheless persisted in a pattern of distributing commonly abused and diverted opioids in geographic areas—and in such quantities, and with such frequency—that they knew or should have known these commonly abused controlled substances were not being prescribed and consumed for legitimate medical purposes.

187. The use of opioids by Arkansas citizens who were addicted or who did not have a medically-necessary purpose could not occur without the knowing cooperation and assistance of the Distributor Defendants. If any of the Distributor Defendants adhered to effective controls to guard against diversion, Arkansas, its citizens, and Plaintiffs would have avoided significant injury.

188. The Distributor Defendants made substantial profits over the years based on the diversion of opioids into Arkansas. Their participation and cooperation in a common enterprise has foreseeably caused injuries the citizens of Arkansas and financial damages to Plaintiffs. The Distributor Defendants knew full well that Arkansas and its citizens, including Plaintiffs, would be unjustly forced to bear the costs of these injuries and damages.

189. The Distributor Defendants' intentional distribution of excessive amounts of prescription opioids to relatively small communities primarily serving Arkansas citizens showed an intentional or reckless disregard for the safety of Arkansas and its citizens. Their conduct poses a continuing threat to the health, safety, and welfare of Arkansas and its citizens.

190. There have been monumental costs associated with the treatment of patients addicted to prescription opioids as well.

191. Nationally, claims involving workers who take opioids are almost four times more likely to reach costs of over $100,000 than claims involving workers without opioids because opioid patients suffer greater side effects and are slower to return to work. Even adjusting for injury severity and self-reported pain score, receiving an opioid for more than seven days and receiving more than one opioid prescription increased the risk that a patient will be on work disability one year later. A prescription for opioids as the first treatment for a workplace injury doubles the average length of the claim.

192. While the use of opioids has taken an enormous toll on the State of Arkansas, its residents, and Plaintiffs, Defendants have realized blockbuster profits. In 2014 alone, opioids generated $11 billion in revenue for drug companies like Defendants. Indeed, financial information indicates that each Defendant experienced a material increase in sales, revenue, and profits from the false and deceptive advertising and other unlawful and unfair conduct described above.

COUNT I
UNJUST ENRICHMENT OR EQUITABLE SUBROGATION
(ALL DEFENDANTS)

193. Defendants entered into and created an overall scheme based upon fraud, deception, and deceit reasonably calculated to deceive consumers, physicians, healthcare providers, and the payors of healthcare-related services and prescriptions for their beneficiaries. As a direct result of

Defendants' actions and with their full knowledge, Defendants' overall scheme caused (1) the over-prescription of opioids, (2) the subsequent addiction to opioids which resulted in services and treatment for that addiction, and/or (3) medical treatment or healthcare related services resulting from adverse reaction to or overdose from opioids.

194. Thus, there are five types of payments for which Plaintiffs through the Trusts became obligated to pay: (a) payment for the over-prescription of the subject opioids, and/or (b) services and treatment resulting from addiction to the subject opioids, and/or (c) medical treatment or healthcare related services resulting from adverse reaction to or overdose from opioids, and/or (d) additional costs incurred to administer plans combating the effects of the opioid crisis, and/or (e) legal fees, judgments, and other costs arising out of litigation against counties for opioid overdoses and adverse reactions to opioids by citizens in the custody of county officials who are beneficiaries of the Trusts. As to all five types of expenditures, Defendants had actual knowledge through their overall scheme that such expenditures would in all likelihood be paid by either the person to whom the prescriptions were written or a responsible third-party like Plaintiffs and their Plans. Plaintiffs and the Trusts paid these expenditures as a debt or obligation on behalf of their beneficiaries.

195. The beneficiaries of Plaintiffs' Plans became primarily liable for the obligations upon which payments were made by Plaintiffs as a proximate result of Defendants' overall scheme to create a market place of addiction (a) necessitating the expenditure of monies for opioid prescription and thereafter, and/or (b) necessitating the expenditure of monies for services and treatment for Plan members' addiction, and/or (c) necessitating the expenditure of monies for services and treatment due to overdose, and/or (d) necessitating the expenditure of monies for fees and costs associated with the administration of plans combating the opioid crisis, and/or (e)

necessitating the expenditure of monies for fees and costs associated with litigation filed by citizens who were in the custody of county officials.

196. The Defendants' overall scheme to create a market place of addiction resulting in the five types of expenditures caused Plaintiffs to make the claimed payments for prescriptions and services which it would not have otherwise been primarily or technically bound to do.

197. In order to protect its own secondary rights and fulfill a contractual obligation to the Trusts' beneficiaries, Plaintiffs were forced to comply with an obligation to expend monies for the (a) payment for over-prescription of the subject opioids, and/or (b) services and treatment resulting from addiction to the subject opioids, and/or (c) medical treatment or healthcare related services resulting from adverse reaction to or overdose from opioids, and/or (d) additional costs incurred to administer plans combating the effects of the opioid crisis, and/or (e) legal fees, judgments, and other costs arising out of litigation against counties for opioid overdoses and adverse reactions to opioids by citizens in the custody of county officials who are beneficiaries of the Trusts—all as a result of Defendants' overall scheme

198. In fulfilling the obligations which Defendants foisted upon the beneficiaries of Plaintiffs' Plans, Plaintiffs did not act as a volunteer or as an intermeddler.

199. As a result of Plaintiffs' action of payment for obligations created as a result of Defendants' overall scheme to create a marketplace based upon fraud, deception, and deceit, Defendants have been unjustly enriched.

200. As a result of Defendants' unjust enrichment, Plaintiffs are entitled to equitable subrogation against Defendants for the return of all monies paid and benefiting Defendants for their actions.

COUNT II
FRAUD
(ALL DEFENDANTS)

201. As alleged throughout this Complaint, Defendants engaged in false representations and concealments of material fact regarding the use of opioids. In doing so, Defendants entered into and created an overall scheme based upon fraud, deception, and deceit reasonably calculated to deceive consumers, physicians, healthcare providers, and the payors of healthcare related services and prescriptions for their beneficiaries. As a direct result of Defendants' actions and with their knowledge, Defendants overall scheme caused (1) the over-prescription of opioids, and/or (2) the subsequent addiction to opioids which resulted in services and treatment for that addiction, and/or (3) medical treatment or healthcare related services resulting from adverse reaction to or overdose from opioids.

202. Through their fraudulent scheme, Defendants foisted upon the beneficiaries of Plaintiffs' Plans five types of monetary obligations: (a) necessitating the expenditure of monies for opioid prescription and thereafter, and/or (b) necessitating the expenditure of monies for services and treatment for Plan members' addiction, and/or (c) necessitating the expenditure of monies for services and treatment due to overdose, and/or (d) necessitating the expenditure of monies for fees and costs associated with the administration of plans combating the opioid crisis, and/or (e) necessitating the expenditure of monies for fees and costs associated with litigation filed by citizens who were in the custody of county officials.

203. Defendants had actual knowledge through their overall scheme that consumers, physicians, healthcare providers, and the payors of healthcare related services and prescriptions for their beneficiaries would rely upon their misrepresentations, deception, and material omissions regarding the use of opioids. Defendants fully intended for consumers, physicians, healthcare

providers, and the payors of healthcare related services and prescriptions for their beneficiaries to rely upon their misrepresentations, deception, and material omissions regarding the use of opioids.

204. Plaintiffs and the Trusts relied upon the insurance marketplace acceptance of the use of opioids based entirely upon Defendants' overall scheme of false representations and concealments of material fact regarding the use of opioids. In doing so, Plaintiffs and the Trusts made payments on behalf of their beneficiaries for (a) the over-prescription of the subject opioids, and/or (b) services and treatment resulting from addiction to the subject opioids, and/or (c) medical treatment or healthcare related services resulting from adverse reaction to or overdose from opioids, and/or (d) additional costs incurred to administer plans combating the effects of the opioid crisis, and/or (e) legal fees, judgments, and other costs arising out of litigation against counties for opioid overdoses and adverse reactions to opioids by citizens in the custody of county officials who are beneficiaries of the Trusts.

205. As a direct and proximate result of Defendants' fraudulent conduct, Plaintiffs and the Trusts have been injured and suffered the loss of hundreds of thousands of dollars, if not millions.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray:

A. That the acts alleged herein be adjudged and decreed to be unlawful in violation of state statutory and common law and that the Court enter a judgment declaring them to be so;

B. That Defendants be enjoined from, directly or indirectly through KOLs, Front Groups or other third parties, continuing to misrepresent the risks and benefits of the use of opioids for chronic pain, and from continuing to violate Arkansas law;

C. That Plaintiffs recover all measures of damages allowable, and that judgment be entered against Defendants in favor of Plaintiffs;

D. That Plaintiffs recover the costs and expenses of suit, pre- and post-judgment interest, and reasonable attorneys' fees as provided by law;

E. That Defendants be ordered to pay punitive and treble damages as provided by law; and

F. That the Court order such other and further relief as the Court deems just, necessary and appropriate.

JURY TRIAL DEMANDED

Plaintiffs demand a trial by jury on all claims to the maximum number of jurors permitted by law.

Respectfully submitted,

DATE: December 14, 2017

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